

K221306 SOLTIVE Pro SuperPulsed Laser, SOLTIVE Premium SuperPulsed Laser, SOLTIVE SuperPulsed Laser Fibers, and AccessoriesJan 27, 2023
267 days to decisionK221306 · Product code: **GEX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k221306/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 5, 2022
Decision date	Jan 27, 2023
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	Jon Gilber
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

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